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10/688,845	10/15/2003	Michael T. Lotze	076333-0393	9535

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Application Number: 10/688,845
Filing Date: October 15, 2003
Appellant(s): LOTZE ET AL.

Stephen A. Bent
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 1/5/09 appealing from the Office action mailed 4/10/08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief. The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Bhardwaj et al., J. Clin. Invest. Vol. 98: 715-722 (1996)

Hackstein et al., Blood, Vol. 100: 1084-1087 (2002)

Kelleher et al., Int'l Immunology, Vol. 10: 749-755 (1998)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 27-29, 31, 35-38 and 40 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bhardwaj et al., 1996, as evidenced by Hackstein et al., 2002.

Bhardwaj et al. disclose a culture (i.e. a composition) comprising ex-vivo purified, antigen unloaded dendritic cells and IL-12 (see pg. 715 and Table 1 in particular). As evidenced by Hackstein et al., dendritic cells arise from CD34+ stem cells, and thus the ex-vivo isolated dendritic cells taught by Bhardwaj et al. are CD34+ derived. It is noted that the term “therapeutic composition” carries little patentable weight in the absence of evidence of a structural difference, since it refers to an intended use of the composition. The culture medium taught by Bhardwaj et al. (RPMI supplemented with gentamicin, human serum and HEPES buffer) is not incompatible with biological activity and therefore meets the limitations of a “physiologically” or “pharmaceutically” acceptable buffer and a “therapeutic composition”.

Claim 27-29, 31, 35-38 and 40 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kelleher et al., 1998.

Kelleher et al. disclose a culture (i.e. a composition) comprising antigen unloaded dendritic cells and IL-12 (see pg. 750 in particular). Kelleher et al. further teach that said dendritic cells are derived from CD34 bone marrow stem cells (see abstract and pg. 750 in particular). It is noted that the term “therapeutic composition” carries little patentable weight in the absence of evidence of a structural difference, since it refers to an intended use of the composition. The culture medium taught by Kelleher et al. (RPMI supplemented with penicillin, streptomycin, glutamine, FCS, and 2 mercaptoethanol) is not incompatible with biological activity and therefore meets the limitations of a “pharmaceutically” or “physiologically” acceptable buffer and a “therapeutic composition”.

(10) Response to Argument

Applicant argues that the claimed preamble of a "therapeutic composition" breaths life and meaning into the claims, and none of the prior art references teach using the dendritic cell compositions therapeutically.

During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference between the claimed invention and the prior art. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention’s limitations, then the preamble is not considered a limitation and is of no significance to claim construction. See MPEP 2111.02. While the prior art does not teach using the dendritic cell compositions therapeutically, the compositions of the prior art meet all the structural requirements of the instant claims (see below). Thus, the dendritic cell compositions of the prior art are capable of performing the intended use recited in the preamble of the instant claims. The instant claims set forth a composition comprising a physiologically or pharmaceutically acceptable solution, a dendritic cell,

and IL-12. The prior art references teach a composition comprising tissue culture medium (i.e. a physiologically or pharmaceutically acceptable solution), dendritic cells, and IL-12. Cells in culture medium are considered to be compatible with physiological conditions and not incompatible with pharmaceutical use. In fact, the instant specification on page 18 specifically states that the use of conventional media as a formulation for administration is contemplated, as long as said media is not incompatible with an active compound of the invention. Clearly, culture media is not incompatible with dendritic cells (i.e. the active compound) since dendritic cells are optimally grown and expanded in said media.

Applicant further argues that the cell cultures of the prior art are not "physiologically compatible" because the cultures contain agents and impurities that are antithetical to a "therapeutic composition", as evidenced by the Lotze declaration.

The only evidence provided by Applicant as to the fact that tissue culture medium does not meet the limitation of a "therapeutic" composition is the declaration of Inventor Lotze. Said declaration states that cell cultures might contain impurities or inhibitory proteins such as IL-10 or TGF-beta, that may cause a reaction in a patient. However, even if present in the cell cultures, cytokines such as IL-10 or TGF-beta would not render a solution to be physiologically incompatible. In fact, dependent claim 31 of the instant application specifically states that the therapeutic composition can comprise TGF-beta or IL-10.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Amy E. Juedes

Examiner, Art Unit 1644

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